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| APPLICATION NO.                                                      | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.                 | CONFIRMATION NO. |
|----------------------------------------------------------------------|-------------|----------------------|-------------------------------------|------------------|
| 10/657,963                                                           | 09/08/2003  | Mark W. Kroll        | A03P1062US02                        | 4136             |
| 36802                                                                | 7590        | 03/08/2006           |                                     |                  |
| PACESETTER, INC.<br>15900 VALLEY VIEW COURT<br>SYLMAR, CA 91392-9221 |             |                      | EXAMINER<br>MALAMUD, DEBORAH LESLIE |                  |
|                                                                      |             |                      | ART UNIT                            | PAPER NUMBER     |
|                                                                      |             |                      | 3766                                |                  |
| DATE MAILED: 03/08/2006                                              |             |                      |                                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

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|                              |                                      |                                     |  |
|------------------------------|--------------------------------------|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/657,963 | <b>Applicant(s)</b><br>KROLL ET AL. |  |
|                              | <b>Examiner</b><br>Deborah Malamud   | <b>Art Unit</b><br>3766             |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 September 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 15-21 is/are rejected.
- 7) ☒ Claim(s) 14 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 September 2003 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                                           |                                                                                         |
|-------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                               | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                                      | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/8/03</u> | 6) <input type="checkbox"/> Other: _____                                                |

## **DETAILED ACTION**

### ***Double Patenting***

1. Claims 1, 15 and 20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 9, 1 and 16 of copending Application No. 10/657,897 (Kroll et al). Although the conflicting claims are not identical, they are not patentably distinct from each other because they both disclose systems and methods of overdrive pacing the heart coupled with antitachycardia pacing.

2. Claims 15 and 20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 9, 1 and 16 of copending Application No. 10/657,840 (Kroll et al). Although the conflicting claims are not identical, they are not patentably distinct from each other because they both disclose systems and methods of overdrive pacing the heart coupled with antitachycardia pacing.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See

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MPEP § 2172.01. The omitted steps are: switching from overdrive pacing to ATP therapy. It appears that the claim is describing the method of switching from preventive overdrive pacing to ATP therapy, then switching from preventive overdrive pacing therapy to ATP therapy again without being in ATP therapy mode. It is unclear when in the automatic switching mode the system is in overdrive pacing mode and when it is in ATP therapy mode.

5. Claim 18 recites the limitation "the initial period of preventive overdrive pacing" in line 3 of the claim. There is insufficient antecedent basis for this limitation in the claim. The examiner recommends correction to "an initial period of preventive overdrive pacing."

### ***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-2, 4- and 18-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Bradley et al (U.S. 2003/0208241). Regarding claims 15 and 20, Bradley discloses (paragraph 0010) "an implantable cardiac stimulation device having a sensing circuit for sensing electrical signals from the heart of a patient, a pulse generator for

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generating pacing pulses for delivery to the heart of the patient, and a control unit. The control unit controls the pulse generator to overdrive pace the heart at an overdrive pacing rate with each pulse set to a standard pacing pulse magnitude. The control unit performs capture verification on each overdrive pacing pulse using signals detected by the sensing circuit. If a pulse fails to evoke capture, the pulse generator is controlled to generate a backup pulse having a pulse magnitude greater than a standard overdrive pulse magnitude for delivery to the heart tissue.” See Figures 2 and 3. The examiner considers this to be a system comprising an overdrive pacing unit, an antitachycardia pacing therapy unit, a capture-based tachycardia detection unit and a control unit operative to perform the claimed functions.

Regarding claims 16 and 21, Bradley discloses in paragraph 0003 that a cardiac stimulation device will sometimes induce artificial tachycardia in order to prevent actual tachycardia during overdrive pacing. This tachycardia will spontaneously terminate, without treatment. If an actual tachycardia occurs, the cardiac stimulation device will sense the tachycardia and immediately begin pacing at a rate of slightly faster than the tachycardia. Therefore the examiner considers that a system such as the one taught by Bradley will inherently enable automatic switching from preventive overdrive pacing to ATP therapy if the percentage does not exceed a predetermined threshold (such as 150 bpm), and disable automatic switching from preventive overdrive pacing to ATP therapy if the percentage exceeds the predetermined threshold.

Regarding claims 18 and 19, Bradley discloses (paragraph 0004) “the stimulation device then overdrive paces the heart at the selected overdrive pacing rate for a dwell

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time consisting of a programmed number of overdrive events or cycles.” Bradley later discloses the use of this “dwell time” as a determination of period of overdrive pacing; as it is based on a programmed number of overdrive events or cycles, it represents an initial period defined by a predetermined period of time, and also by a predetermined number of cardiac episodes.

Regarding claims 1-2 and 4-5, in view of the structure as disclosed by Bradley, the method of operating or using the device would be inherent because it is the normal and logical means by which the device can be used.

Regarding claim 6, the examiner considers the device shown in Figure 1 to represent an implantable cardiac stimulation device. It is inherent in the system that the pacing and detection of events would take place soon after implantation.

Regarding claim 7, Bradley discloses (paragraph 0011) “the standard overdrive pulse magnitude is determined by performing an automatic capture threshold detection search. The threshold detection search may be performed, for example, whenever two consecutive overdrive pulses fail to evoke capture or may be performed periodically.” The examiner considers this to be performing the method periodically.

Regarding claim 8, the method illustrated in Figure 3 discloses a repetitive treatment. The examiner considers this to be a method that repeats itself in the manner claimed.

Regarding claim 9, Bradley discloses (paragraph 0013) a rate recovery technique, where overdrive rate is reduced following a sequence of overdrive pacing pulses “capture detection is maintained during rate recovery but the pulse magnitude is

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increased to the HOM [high output mode] voltage. Once the output is increased to HOM, subsequent LOCs are considered to be intrinsic P-waves. When a predetermined number of P-waves are detected, the rate is increased." The examiner considers this to be a preventive overdrive pacing unit that delivers pacing pulses at a predetermined maximum pulse magnitude; the tachycardia detection unit detects tachycardia based upon the LOC of one or more pacing pulses.

Regarding claim 10, Bradley discloses (paragraph 0012) "when a predetermined number of intrinsic beats are detected, the overdrive rate is increased. The overdrive pulse magnitude is maintained at the elevated pulse magnitude for the next two beats and a full capture assessment is performed. If capture is detected, then the pulse magnitude is incrementally reduced over the next two beats. If capture is not detected, the overdrive rate is not increased; rather the pulse amplitude is immediately increased to a high-output mode (HOM) voltage (e.g. 4.5V)." The examiner considers this to be delivering pacing pulses at a pulse magnitude less than a predetermined pulse magnitude; the tachycardia detection unit detects tachycardia based upon loss of capture of a pacing pulse and a subsequent backup pulse delivered at the maximum pulse magnitude.

Regarding claim 11, Bradley discloses (paragraph 0011) "the standard overdrive pulse magnitude is determined by performing an automatic capture threshold detection search." Bradley further discloses "a back-up pulse is issued after every beat that is not captured during the capture threshold assessment. By providing for automatic capture threshold detection searches, the standard pulse magnitude of the overdrive pulses can

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be kept as low as possible while still ensuring that substantially all overdrive pulses are properly captured such that backup pulses are not often needed.” The examiner considers this to be an automatic stimulation threshold search unit that performs a stimulation threshold search if a pacing pulse is not captured during preventive overdrive pacing but a backup pulse is captured.

Regarding claim 12, the examiner considers the cardiac stimulation device of Figure 1 to be delivering preventive overdrive pacing to the atria.

### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 3 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bradley et al (U.S. 2003/0208241). Bradley discloses the claimed invention except for the predetermined threshold of 60%. It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize the predetermined threshold of 60%, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

10. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bradley et al (U.S. 2003/0208241) in view of Levine et al (U.S. 6,058,328). Levine discloses



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(column 26, lines 14-23) "if atrial pacing is being provided at 70 bpm, and if a premature atrial contraction (PAC) occurs which changes the effective rate to 74 bpm, then the negative hysteresis feature automatically steps in to increase the atrial paced rate (shorten the atrial escape interval) by, e.g., 5%. Such increased atrial rate is maintained for a prescribed number of cardiac cycles (e.g., 32-256) or for a prescribed time (e.g., 1-5 minutes), at which time the paced rate may be gradually decreased to a prescribed rate (e.g., to a value that is 5-1000 lower than the current paced rate), or gradually decreased until an intrinsic P-wave is sensed." The examiner considers this to teach a PAC detection unit, wherein the control unit is operative to switch from preventive atrial overdrive pacing and to atrial ATP therapy upon the detection of a loss of capture of a backup pulse delivered subsequent to detection of a PAC during preventive overdrive pacing.

### ***Allowable Subject Matter***

11. Claim 14 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Conclusion***

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Malamud whose telephone number is (571) 272-2106. The examiner can normally be reached on Monday-Friday, 8.00am-5.30pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571)272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert E Pezzuto  
Supervisory Patent Examiner  
Art Unit 3766



Deborah L. Malamud  
Patent Examiner  
Art Unit 3766